

JAN 22 1997

K963702

This 510(k) summary of safety and effectiveness information is being submitted in accordance with the requirements of the Safe Medical Devices Act of 1990.

1. **Trade Name:** ACS HI-TORQUE IRON MAN™ Guide Wire

Common Name: Guide Wire

2. **Device Classification:** Vascular Guide Wire

3. **Performance Standards:**

Performance standards have not been established under Section 514 of the Federal Food, Drug, and Cosmetic Act for vascular guide wires.

4. **Device Description:**

ACS HI-TORQUE EXTRA IRON MAN™ Guide Wire

The HI-TORQUE IRON MAN™ Guide Wire is a steerable guide wire intended to facilitate placement of balloon dilatation catheters during Percutaneous Transluminal Coronary Angioplasty (PTCA) and Percutaneous Transluminal Angioplasty (PTA). The wire is also intended to facilitate the placement of equipment, such as atherectomy and compatible stent devices, during other diagnostic and therapeutic intravascular procedures. It is not intended for use in the cerebral vasculature.

The proximal and distal portions of the guide wire are constructed from a core assembly. A series of tapers and flats, which reduce the diameter of the core wire distally, yields the desired tip flexibility. The distal 12 to 15 centimeters proximal to the tip of the ACS HI-TORQUE IRON MAN™ Guide Wire are coated with Microglide® while the remaining portion is coated with polytetrafluoroethylene (PTFE). Both coatings are intended to reduce friction for improved movement of the wire within the catheter. The platinum alloy coils provide the physicians with a radiopaque tip.

5. **Summary of Substantial Equivalence:**

A comparison of the ACS HI-TORQUE IRON MAN™ Guide Wire to the predicate ACS Hi-Torque Extra S'Port™ Guide Wire (K942066, July 18, 1994 and K950156, April 5, 1995), indicates that the new guide wire is substantially equivalent to the predicate guide wire with regard to the intended use, materials and design. In addition, the ACS HI-TORQUE IRON MAN™ is substantially equivalent to the Boston Scientific Corporation .014" Platinum Plus™ Guide Wire with regard to the functional dimensions of rotational accuracy and tip flexibility.

The HI-TORQUE IRON MAN™ Guide Wire is a steerable guide wire intended to facilitate placement of balloon dilatation catheters during Percutaneous Transluminal Coronary Angioplasty (PTCA) and Percutaneous Transluminal Angioplasty (PTA). The wire is also intended to facilitate the placement of equipment, such as atherectomy and compatible stent devices, during other diagnostic and therapeutic intravascular procedures. It is not intended for use in the cerebral vasculature. The intended use of the HI-TORQUE IRON MAN™ Guide Wire is equivalent to the predicate guide wires noted above.

The materials used in the manufacture of the HI-TORQUE IRON MAN™ Guide Wire are identical to those in the predicate Hi-Torque Extra S'Port™ Guide Wire.

The design of the new ACS HI-TORQUE IRON MAN™ Guide Wire is constructed from a stainless steel core wire. Like the predicate ACS Hi-Torque Extra S'Port™ guide wire, the new guide wire design includes a series of tapers and flats which reduce the diameter of the core wire distally, yielding the desired tip flexibility. Like the predicate ACS Hi-Torque Extra S'Port™ guide wire the intermediate coils are eliminated in the new design. Unlike the ACS Hi-Torque Extra S'Port™ Guide Wire, the ACS HI-TORQUE IRON MAN™ wire diameters and tapers along the length of the distal portion of the guide wire have been modified to yield the desired support over the distal 30 centimeters of the wire. This modification involves no new materials or processes in comparison to the predicate wire, the ACS Hi-Torque Extra S'Port™ Guide Wire and has no effect on the distal tip of the guide wire. Therefore, the tapers and diameters positioned at different locations proximal to the tip cannot significantly impact the safety or effectiveness of the guide wire.

6. **Testing Data:**

Biocompatibility

Since the materials for the HI-TORQUE IRON MAN™ Guide Wire are identical to those of the predicate Hi-Torque Extra S'Port™ Guide Wire, the biocompatibility data from the predicate device were used to demonstrate that the

materials and processes utilized in the new guide wire are biocompatible for short term use within the vascular system.

In vivo Testing:

Two animal studies were completed to evaluate and compare the performance of the ACS HI-TORQUE IRON MAN™ Guide Wire to that of the ACS Hi-Torque Extra S'Port™ Guide Wire (K942066, July 18, 1994 and K950156, April 5, 1995) and the Boston Scientific Corporation .014" Platinum Plus Guide Wire (K935997, June 17, 1994), when used in combination with the JJIS Stent Delivery System, ACS TX 2000 Balloon Dilatation Catheter and the DVI AtheroCath-GTO Atherectomy Catheter. The results of these studies show that the ACS HI-TORQUE IRON MAN™ Guide Wire as well as or better than the S'Port and Platinum Plus wires in the majority of the performance parameters when used with the GTO catheter, TX 2000 catheter and the JJIS Stent Delivery System.

Bench Testing

The tensile strengths of the guide wire distal tip were determined by a pull test. These tests demonstrated that the HI-TORQUE IRON MAN™ Guide Wire has adequate tensile strength.

The torsional strength of the distal tip was determined by a turns-to-failure test. This test showed that the HI-TORQUE IRON MAN™ Guide Wire has adequate torsional tip strength.

The correlation between rotation of the proximal end and the corresponding rotation of the distal end of the guide wire was determined by the rotational accuracy test. This test showed that the ACS HI-TORQUE IRON MAN™ Guide Wire has an adequate torque response.

The tip flexibility testing demonstrated that tip flexibility of the ACS HI-TORQUE IRON MAN™ Guide Wire is equivalent to that of the predicate and is acceptable.

7. Sterilization:

The ACS HI-TORQUE IRON MAN™ Guide Wire is sterilized by the same methods and following the same parameters as those used for the predicate ACS Hi-Torque Extra S'Port™ Guide Wire (K942066, 7/18/94 and K950156, 4/5/95).

8. Conclusion:

The HI-TORQUE IRON MAN™ Guide Wire is substantially equivalent to the predicate ACS Hi-Torque Extra S'Port™ Guide Wire (K942066, 4/28/94 and

K950156, 1/16/95) and the Boston Scientific Corporation .014" Platinum Plus™
Guide Wire (K935997, 6/17/94).

Signed:

A handwritten signature in cursive script, appearing to read "Kevin Corrigan", written over a horizontal line.

Kevin Corrigan
Manager, Regulatory Affairs